

II. Remarks

A. Status of the Claims

Claims 1-25 will be pending after entry of this amendment. Claims 1-3, 7-8, 10-15 and 21-25 have been amended herein without prejudice. Claims 18-21 and 23 were previously withdrawn. Claims 26-28 have been cancelled without prejudice. Support for the amendments to claims 1-3, 7-8, 10-13, 15 and 21-25 can be found throughout the application as originally filed, specifically, e.g., in the original filed claims and paragraphs [0006], [0015] and [0032] of the specification. Applicants respectfully submit that no new matter has been added by virtue of this amendment.

B. Oath/Declaration

In the Office Action, the Examiner indicated that the oath or declaration was defective.

Applicants note that they are currently in the process of obtaining a newly executed declaration from the inventors.

C. Claim Objections

In the Office Action, the Examiner objected to claim 14 for containing two periods at the end of the claim.

In response, claim 14 has been amended to remove the duplicate punctuation. Accordingly, Applicants request that the objection be removed.

D. Current Rejections/Amended Claims

Prior to addressing the rejections, Applicants respectfully point out that the claims have been amended without prejudice to recite a method of inducing structural damage in a target cell, as represented below by independent claim 1:

*A method of inducing structural damage in a target cell
comprising the steps of:
 providing particles comprising one or more
 nanoparticles of magnetic material;
 contacting the particles with the target cell; and
 applying a magnetic field to the particles to induce
 motion of the particles, whereby the motion of the particles in
 contact with the target cell inflicts structural damage to the
 target cell.*

Applicants respectfully submit that the current amendments are not to be viewed as an admission of the propriety of the rejections. Applicants will address the current rejections as applied to the currently amended claims.

E. Claim Rejections Under 35 U.S.C. § 112, first paragraph

In the Office Action, claims 1-11, 13-17, 21, 22, 24 and 25 were rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking enablement.

This rejection is traversed as it is applied to the currently amended claims. Applicants submit that, as admitted by the Examiner, the present specification teaches “magneto-mechanical disturbance of cell structure...magnetically activated drug release at local regions...from a magnetic particle-containing drug reservoir...that nanoscale magnetic particles can be targeted to diseased cells by tagging with biomolecules, guided with external magnetic fields, transfer energy for hypothermia, and be detected by MRI...” and “that

magnetic particles move in a magnetic field and thus can be made to rotate or oscillate laterally back and forth". *Office Action* at page 4. Applicants further submit that an example has been provided in paragraph [0032] of the Specification, accompanied by illustrative figures (e.g., Figures 3(b), 3(d), 4(a) and 4(b)) of how the movement of the nanoparticles would cause structural damage to the cell. Applicants submit that this descriptive support coupled with the knowledge of a skilled artisan would enable one to make and use the invention commensurate with the scope of the present claims.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be removed.

F. Claim Rejections Under 35 U.S.C. § 102

1. Alexiou 1

In the Office Action, claims 1-7, 10 and 11 were rejected under 35 U.S.C. § 102(a) as being anticipated by *J. Drug Targeting*, April 2003, 11:139-149 by Alexiou et al. (hereinafter "Alexiou 1").

This rejection is respectfully traversed. Pursuant to MPEP § 2131, in order to anticipate and reject a claim under the provisions of 35 U.S.C. § 102, a reference must teach every element of the claim. It is well-established that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987).

Applicants submit that Alexiou 1 specifically fails to teach each and every step set

forth in the present claims, specifically the step of applying a magnetic field to the particles to induce motion of the particles, whereby the motion of the particles in contact with the target cell inflicts structural damage to the target cell.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be removed.

2. Alexiou 1 and Alexiou 2

In the Office Action, claims 1-11 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Cancer Research*, Dec. 2000, 60:6641-6648 to Alexiou et al. (hereinafter “Alexiou 2”), as evidenced by Alexiou 1.

This rejection is respectfully traversed. Applicants submit that Alexiou 2, as evidenced by Alexiou 1, specifically fails to teach each and every step set forth in the present claims, specifically the step of applying a magnetic field to the particles to induce motion of the particles, whereby the motion of the particles in contact with the target cell inflicts structural damage to the target cell.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be removed.

G. Claim Rejections Under 35 U.S.C. § 103

In the Office Action, claims 16, 17, 22, 24 and 25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Alexiou 2 as applied to claim 1-11 above, in view of *J. Controlled Release* 2000, 65: 93-103 to Chung et al. (hereinafter “Chung”), in view of *J. Magnetism and Magnetic Materials*, 2001, 225:118-126 to Jordan et al. (hereinafter

“Jordan”), and in view of *Jpn. J. Cancer Res.*, 92:1138-1146 to Shinkai et al.

This rejection is respectfully traversed. Applicants submit that the combined teachings of Alexiou 2, Chung, Jordan and Shinkai fail to render obvious the method of inducing structural damage in a target cell, as presently claimed. Pursuant to MPEP § 2142, to establish a prima facie case of obviousness, and thus sustain the rejection of a claim under 35 U.S.C. § 103(a), there must be a clear articulation of the reasons why Applicants’ claimed invention would have been obvious. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Supreme Court in *KSR* has further noted that an analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit. Therefore, it is clear that an obviousness rejection “cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006). Moreover, “[t]o support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” MPEP § 706.02(j).

Specifically, Applicants submit that the combination of Alexiou 2, Chung, Jordan and Shinkai fail to obviate the claimed limitation of applying a magnetic field to the particles to induce motion of the particles, whereby the motion of the particles in contact with the target cell inflicts structural damage to the target cell.

Applicants respectfully point out that the Examiner’s rejections are based on the previously presented independent claim which recited that the method of the invention

includes the steps of *magnetically induced motion of the nanoparticles or magnetically inducing release of the medication*. The Examiner focused the rejection solely on the limitation of *magnetically inducing release of the medication*. However, the present claims have been amended to recite that the method requires the step of *magnetically induced motion of the nanoparticles*, and the alternative language has been deleted. Therefore, Applicants submit that the combination of the cited references fail to make obvious the step of applying a magnetic field to the particles to induce motion of the particles, whereby the motion of the particles in contact with the target cell inflicts structural damage to the target cell, and the Examiner has failed to provide evidence to the contrary.

Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be removed.

III. Conclusion

In view of the amendments made and arguments presented, it is believed that all claims are in condition for allowance. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is invited to telephone the undersigned at (973)597-6162. The undersigned also may be contacted via email at epietrowski@lowenstein.com. All correspondence should be directed to our address listed below.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees that may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,

Date: September 8, 2009

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